



PATENT

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3-12-02

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Thomas L. MEREDITH

Serial No.: 09/615,643

Group: 3738

Filed: July 13, 2001

Examiner: B. Pellegrino

Atty. Docket No.: N6089 RSM

Customer Number: 23456

For: COMPOSITE BONE MATERIAL IMPLANT AND PROSTHESIS

DECLARATION UNDER 37 C.F.R. § 1.131

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Thomas L. Meredith, Applicant in the above-identified application,
declares as follows:

(1) I have read and understand the Office Action mailed on
December 18, 2001 in connection with the above-identified application.
More specifically, I have read and understood the Boyce, et al. patent
(U.S. 6,294,187), cited by the Examiner. I understand that the Boyce, et
al. patent issued on September 25, 2001, and has an effective filing date
of February 23, 1999.

(2) Prior to February 23, 1999, I conceived and reduced to practice the invention that is the subject matter of the above-identified application, as evidenced by the attachments submitted herewith.

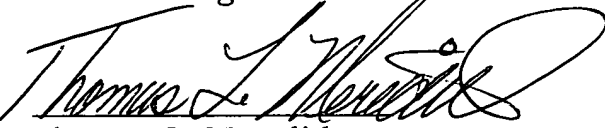
(3) Attachment A is a letter dated September 11, 1996, which describes a proposed course of action with respect to the eventual subject matter of the present application. The letter describes sintering "grinding" cortical bone, possible binders associated with the sintered cortical bone, testing for density, and molding.

(4) Attachment B is a memo dated January 19, 1999 describing results obtained with a bone composite that was ground and molded according to the present invention. Additionally, the purpose of the memo was to record outstanding results with respect to (Pasco-Fix) cyanoacrylate binder.

(5) As can be seen by the attachments, it is clear that the present invention was conceived and reduced to practice prior to the effective filing date of the Boyce, et al. patent relied upon by the Examiner in the outstanding Office Action.

(6) I further state that the above statements were made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under § 1001 of Title XVIII of the U.S.

Code, and any such willful false statements may jeopardize the
validity of this application or any patent resulting therefrom.


Thomas L. Meredith

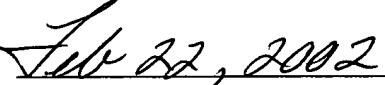

Date



EXHIBIT D

THOMAS MATTHEW INDUSTRIES, INC.

405 OWENDALE DR. • ANTIOCH, TENNESSEE 37013

OFFICE: (615) 361-3054 • FAX: (615) 361-3054

line 366-4090

Sept 11, 1996

CONFIDENTIAL

Tennessee Donor Services
1714 Hayes St
Nashville, Tennessee 37203

ATTN: Mr. John Lee, Director of Tissue Services.

REF: Our meeting of Sept 4, 1996., and possible development
of sintered cortical bone fasteners/adapters.

"Proposal"

Dear John,

After our last meeting and discussion on the feasibility of developing parts (fasteners/adapters) from a sintered cortical bone process; I am encouraged over the medical benefits of such a product.

Sintered solid metals has been used successfully within industrial markets for years. applying this same technology toward cortical bone products can be a winning combination with TDS human tissue expertise and Thomas Matthew Industries, Inc., industrial engineering and manufacturing capabilities. therefore I am proposing the following:

1. That TDS & TMI shall jointly commence with engineering and laboratory research on a sintered human bone (cortical) fastener/adaptor product.
2. Product research to be directed toward retention of bone morphogenetic protein while subjecting powdered cortical bone to various (+) temperatures, pressures and time.
3. Possible binders to be tested with #2.
4. Density, brinell hardness, tensile strength, elongation and yield strength factors to be favorably matched with live cortical bone characteristics.
5. Final product shall replace present metal fastener/adaptor products now used in orthopedic surgery.
6. Final product shall be molded in total (threads are not chased), then tested, quality inspected and packaged.

(Continued)

ATTACHMENT A

Pg 2. (Continued)

Tennessee Donor Services - "Proposal"

CONFIDENTIAL

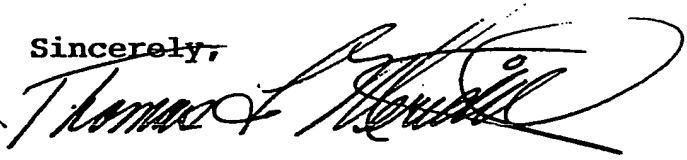
Further Conditions:

1. TMI to cover all development cost, not including patent search, application for patent pending, attorney fees, supply of powdered cortical bone and possible binders.
2. TMI to design and manufacture metal research molds.
3. TMI to supply equipment such as heat elements, high pressure pumps, compressors, instrumentation to test tensile strength and engineering drawings.
4. TDS shall maintain exclusive marketing rights.
5. TDS shall hold all patents in the name of TDS plus TMI as inventor.
6. TDS shall have rights of first refusal toward any related future products.
7. TMI shall have exclusive manufacturing rights.
8. TMI may negotiate selling rights with TDS approval only.

Estimated cost of development is in the range of \$ 50,000.00 dollars, including time and labor. This may be paid to TMI on a monthly basis. Target dates for completion of this project need to be discussed with TDS as is a definite cost of development.

Anxiously awaiting your reply.

Sincerely,



Thomas L. Meredith
President
Thomas Matthew Industries, Inc.

1/19/1999

12:55

11:45 Impregnate Semi Circular Bone Disc ^{3.5cc} found at 192 Kpsi
during last experiment, with PASCO-Fix "Organic Adhesive"
Disc observed @ 12:45 Disc stable unable to break with
compressive force.

will work to ID Adhesive & Tensile

Thomas [Signature]

ATTACHMENT B